UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-CV-12257 PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris Chief Magistrate Judge Marianne B. Bowler

THE BMS DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

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Preliminary Statement

On March 15, 2006, both the BMS defendants[1] and plaintiffs moved for summary judgment.[2] BMS's motion is based on certain undisputed facts with respect to the seven "subject" cancer drugs at issue in this case:

(1) BMS has never reported average wholesale prices; rather, BMS has always reported wholesale list prices ("WLPs") that reflect the actual prices that appear on invoices to wholesalers and are the prices at which BMS achieves the overwhelming proportion of its revenue.

(2) BMS does not control the calculation or dissemination of AWPs by independent industry publications such as the Red Book.

(3) To the extent that BMS has discussed "spreads" with customers, those discussions have involved nothing more than conveying truthful information to customers about the financial consequences of their transactions.

(4) Medicare knew the spreads of certain BMS drugs at issue and nevertheless continued to use AWP as a reimbursement benchmark.

These facts establish that BMS could not have violated any of the consumer fraud statutes under which plaintiffs sue.

Plaintiffs' motion in no way controverts any of these essential facts; rather plaintiffs make a number of factual assertions that are either unsupported or irrelevant. For

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[1] The BMS defendants include Bristol-Myers Squibb Co. ("BMS") and its former subsidiaries Oncology Therapeutics Network Corp. ("OTN") and Apothecon, Inc. ("Apothecon"). OTN was a specialty distributor of oncology drugs for numerous manufacturers, including BMS. Apothecon marketed generic drugs. The BMS defendants will be referred to collectively as BMS.

[2] In support of its motion, BMS submitted the affidavit of Denise M. Kaszuba, sworn to February 18, 2004 ("Kaszuba Aff."), the declaration of Zoltan Szabo, dated October 25, 2004 ("Szabo Decl."), the declaration of Steven M. Edwards, dated March 15, 2006 ("Edwards Decl.") and the expert declaration of Dr. Gregory K. Bell, Ph.D. dated March 15, 2006 ("Bell BMS Decl."). BMS proffers that evidence, as well as the evidence attached to the declaration of Lyndon M. Tretter, dated April 6, 2006 ("Tretter Decl.") in opposition to plaintiffs' motion.

example, plaintiffs assert in conclusory fashion that BMS "controls" AWPs (Pltfs.' Mem. at 15), even though the documents and testimony on which they rely conclusively establish that the publications, not BMS, determine the mark-up factor for calculating AWP. Plaintiffs also rely on numerous documents relating to generic drugs marketed by BMS's Apothecon subsidiary (id. at 17; Pltfs.' BMS Exhs. 9, 19, 22, 27), even though none of those drugs is at issue in the case and the testimony conclusively establishes that the pricing for those drugs was different from the pricing of the drugs at issue in the case. In addition, plaintiffs complain about "secret discounting and rebating mechanisms" (id. at 55), as though discounting should not be secret and price competition somehow violates the law.

Plaintiffs also make a number of legal assertions that are unsupported and incorrect. Contrary to what plaintiffs suggest:

(1) A manufacturer is not responsible for statements by third parties that the manufacturer does not endorse and cannot control.

(2) A manufacturer is not obligated to reduce list prices to reflect discounts.

(3) Providing a customer with truthful information about the financial consequences of a transaction is neither deceptive nor unfair.

(4) Medicare could not have been deceived if it knew the truth.

Plaintiffs' legal theories, if accepted by the Court, would radically change the way companies do business in the United States.

BMS submits that, on the undisputed facts and the law, the Court should grant summary judgment in BMS's favor. If the Court finds that there are genuine issues with respect to the facts that BMS has proffered, however, then it must also find that there are genuine issues

with respect to the same facts as proffered by plaintiffs. It cannot be the case that there are issues with respect to BMS's facts but not plaintiffs' facts.

Statement of Facts

A. BMS Pricing

When BMS launches a product, it establishes a list price. (See Szabo Decl. ¶ 2.) That list price appears on invoices to wholesalers, and most of the sales to customers while a product is protected by a patent are within 5% of that price. (Id. ¶¶ 2-3; Bell BMS Decl. Exh. D.) During the time that a product is protected by a patent, BMS may increase its list price, but it does not do so unless it believes it can obtain sales at the new price, and for the drugs at issue in this case, it has been successful in obtaining sales at or near the increased list price. (Szabo Decl. ¶ 3; Bell BMS Decl. Exh. E.)

After a drug loses patent protection, BMS generally does not make further changes to its list price. (Szabo Decl. ¶ 4.) BMS may offer discounts or rebates to certain customers in order to meet generic competition. (Id.) Even when that happens, however, BMS almost always continues to make significant sales within 5% of list price. (Bell BMS Decl. Exh. E.)

B. BMS Price Reporting

BMS reports its list prices to industry publications such as Red Book, First Data Bank and MediSpan. (Kaszuba Aff. ¶ 1.) BMS has never communicated AWPs to the publications. (Id. ¶ 2; see also Szabo Dep. Tr. 133, 135-36, 151, annexed to Edwards Decl. as Exh. B.) The publications calculate AWPs on their own by multiplying the list price by a mark-up factor ranging from 20% to 25%. (Kaszuba Aff. ¶ 2; Kaszuba Dep. Tr. 97-101, annexed to Edwards Decl. as Exh. C.)

BMS does not control the mark-up factor that the publications use to calculate AWPs. (Morgan Dep. Tr. 230, annexed to Edwards Decl. as Exh. D.) While once – in 1992 – BMS asked the publications to change their mark-up factor on oncology products from 20.5% to 25%, only Red Book acceded to that request; First Data Bank and MediSpan refused. (Kaszuba Aff. ¶ 3.) In 2002, First Data Bank unilaterally changed the mark-up factor for all drugs to 25%, but the other publications did not follow suit (id. ¶ 4) – further demonstrating that BMS does not control AWPs.[3]

Beginning in 1999, BMS began to include language in its communications to publications notifying them that some customers receive manufacturer discounts or rebates that are not reflected in BMS's list prices. (Szabo Decl. ¶ 5.) An example shown to Kay Morgan of First Data Bank at her deposition states:

> Wholesale and Direct List Prices, including those for the products listed herein, may not reflect actual Bristol-Myers Squibb sale prices. Certain multisource products are always sold at lower special offer prices. All products may be subject to negotiated discounts, rebates and chargebacks.

(Morgan Dep. Exh. 41, annexed to Edwards Decl. as Exh. F.) Ms. Morgan testified that, to her knowledge, this information had no impact on the way First Data Bank calculated AWPs. (Morgan Dep. Tr. 227, annexed to Edwards Decl. as Exh. D.)

C. BMS Sales Efforts

Plaintiffs took the depositions of nine BMS sales representatives in the case.[4] The testimony of those witnesses was uniform and consistent: the BMS sales representatives emphasized the therapeutic attributes of the drugs, but when asked questions about

[3] Various BMS documents confirming that the publications control AWPs are annexed to the Edwards Declaration as Exhibit E. First DataBank documents confirming this point are annexed to the Tretter Declaration as Exhs. 2-4.

[4] Raul Armand, Gena Gook, Dana Faulkner, Greg Keighley, Thomas Liptak, Marsha Peterson, Fran Morrison, Joe Petrella and Douglas Soule. Excerpts from those depositions are annexed to the Edwards declaration as Exhibit G.

reimbursement they responded with truthful information. (Edwards Decl. ¶ 8, Exh. G.) There is no evidence that BMS "manipulated" AWPs and then told its sales representatives to promote the spread as a reason to purchase its products.

D. Plaintiffs' Facts

Plaintiffs do not dispute BMS's facts. Rather, plaintiffs allege, in the first instance, that BMS agrees that AWP was the reimbursement mechanism for Medicare Part B. (Pltfs.' Mem. at 6.) There is no material dispute about this. With certain exceptions and variations, Medicare used AWP as a reimbursement benchmark for physician-administered drugs.[5]

Plaintiffs also allege that BMS "caused" AWPs to be published because it (a) sent its list prices to the publications; (b) asked the publications to supply AWPs back to BMS; and (c) reviewed the AWPs to determine whether they were accurate. (Pltfs.' Mem. at 15-16.)[6] Plaintiffs further allege that BMS was well aware of the mark-up factors the publications were applying to list prices in order to arrive at AWPs. (Id. at 16-17.) Except for the characterization that BMS "caused" AWPs to be published, which is a legal conclusion, not a fact, there is no real dispute as to these facts; BMS simply states that, as a matter of law, these facts do not make it responsible for the publications' markups.

In addition, plaintiffs rely on a number of Apothecon documents in an effort to suggest that BMS did not achieve sales at list price. (Pltfs.' Mem. at 17; see e.g., Pltfs.' BMS Exhs. 9, 19, 22, 27.) As noted above, however, these documents relate to generic self-administered drugs – none of which is at issue in the case. (Kaszuba Dep. Tr. 209-11, annexed

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[5] Medicare also used the physician's actual charge and, for multi-source drugs, the median AWP. See 42 C.F.R. § 405.517.

[6] Plaintiffs point to a document that states that AWPs were reviewed for "reasonability," but the document makes clear that the review was limited to determining whether the publications' math was correct. (Pltfs.' BMS Exh. 16.)

to Tretter Decl. as Exh. 1.) The BMS drugs at issue in the case had significant sales within 5% of list price. (Szabo Decl. ¶¶ 2, 11; Bell BMS Decl. ¶ 31.)

Plaintiffs refer to a number of internal and external BMS documents that identify AWPs or spreads, including the Internal Price List, the Pocket Reference Guide, The Network News and the AWP Report. (Pltfs.' Mem. at 18-19.) Plaintiffs also point out that reimbursement information was made available to customers in the form of a reimbursement hotline, a program called ProCert and presentations by sales representatives, which they were trained to make. (Id. at 55-57, 65-68.) Again, there is no real dispute about the facts; BMS simply states that, as a matter of law, those communications cannot give rise to liability.

Finally, plaintiffs assert that BMS knew that subject drugs were sold at prices well below AWP through what it characterizes as "secret discounting and rebating mechanisms." (Pltfs.' Mem. at 52-55, 58-61.) In making this point, plaintiffs again rely, in part, on documents relating to Apothecon drugs that have nothing to do with this case. (Id. at 60-61: atenolol and albuterol.) There is no real dispute that BMS offered discounts, particularly when drugs were subject to generic competition, and in some cases the spreads were significant.

Argument

I.

THE RELEVANT LEGAL STANDARDS

A. Summary Judgment Standards

To prevail on a motion for summary judgment, a plaintiff must come forward with admissible evidence that would permit a reasonable jury to decide the elements of the plaintiff's claim in its favor and would entitle it to a directed verdict if not controverted at trial. Alves v. Harvard Pilgrim Health Care, Inc., 204 F. Supp. 2d 198, 204-205 (D. Mass. 2002).

Conclusions, or factual assertions not supported by admissible evidence, are not sufficient to sustain a party's burden on a motion for summary judgment. See James L. Miniter Ins. Agency, Inc. v. Ohio Indem. Co., 112 F.3d 1240, 1245 (1st Cir. 1997). In addition, facts that have no bearing on the ultimate outcome are irrelevant for purposes of a motion for summary judgment. Ball v. Wal-Mart, Inc., 102 F. Supp. 2d 44, 48 (D. Mass. 2000).

Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party to demonstrate that there is a genuine issue of material fact. Alves, 204 F. Supp. 2d at 204. Again, only material facts count. Flomeh-Mawutor v. Banknorth, N.A., 350 F. Supp. 2d 314, 318 (D. Mass. 2004). Where both sides have moved for summary judgment, "a court must rule on each motion independently, deciding in each instance whether the moving party has met its burden under Rule 56." Salisbury v. Monumental Life Ins. Co., 1 F. Supp. 2d, 97, 100 (D. Mass. 1998) (internal quotations omitted).

B. Elements Of Plaintiffs' Mass. G. L. ch. 93A Claim

While plaintiffs have asserted claims on behalf of Class 1 under the consumer protection statutes of 41 states and the District of Columbia, it makes sense to analyze plaintiffs' claims under Mass. G. L. ch. 93A in the first instance to determine if plaintiffs have a viable claim. If either party is entitled to summary judgment under Mass. G.L. ch. 93A, it may not be necessary to analyze the other statutes. Mass. G.L. ch. 93A statute prohibits "[u]nfair or deceptive acts or practices."

An act or practice is unfair if it (1) violates a "common law, statutory, or other concept of unfairness" or (2) is "immoral, oppressive or unscrupulous." Saint-Gobain Indus. Ceramics Inc. v. Wellons, Inc., 246 F.3d 64, 73 (1st Cir. 2001). While violation of a statute can constitute an unfair act or practice, a violation of a statute is not automatically actionable under

Mass. G.L. ch. 93A. Brazas Sporting Arms, Inc. v. Am. Empire Surplus Lines Ins. Co., 220 F.3d 1, 9 (1st Cir. 2000). For example, where, as here, both the plaintiff and the defendant are engaged in commerce (i.e., the plaintiff is not acting as an ordinary consumer), the plaintiff must show that the defendant's conduct is so objectionable that it has "'attain[ed] a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce.'" Quaker State Oil Refining Corp. v. Garrity Oil Co., 884 F.2d 1510, 1513 (1st Cir. 1989) (quoting Levings v. Forbes & Wallace, Inc., 8 Mass. App. Ct. 498, 504, 396 N.E.2d 149, 153 (1979)). The Massachusetts consumer protection statute "'does not contemplate an overly precious standard of ethical or moral behavior. It is the standard of the commercial market place.'" USM Corp. v. Arthur D. Little Sys., Inc., 28 Mass. App. Ct. 108, 124, 546 N.E.2d 888, 897 (Essex Cty. 1989) (quoting Wassserman v. Agnastopoulos, 22 Mass. App. Ct. 672, 679, 497 N.E.2d 19, 24 (Middlesex Cty. 1986)).

A practice is deceptive if it has the "'capacity or tendency or effect of deceiving buyers or prospective buyers in any material respect.'" Abruzzi Foods, Inc. v. Pasta & Cheese, Inc., 986 F.2d 605, 605 (1st Cir. 1993) (quoting 940 Mass. Code Regs. 3.05 (2006)). A plaintiff cannot succeed on a deception claim if it knew the truth. Dinjian v. Dinjian, 22 Mass. App. Ct. 589, 597, 495 N.E.2d 882, 888 (Middlesex Cty. 1986). Even where a plaintiff claims not to have known the truth, it cannot succeed if a "reasonable" person would not have been misled. See Brazas, 220 F.3d at 9. Furthermore, in order to succeed, a plaintiff must demonstrate that there is a causal connection between the seller's deception and the buyer's loss. Hershenow v. Enter. Rent-A-Car Co. of Boston, Inc., 445 Mass. 790, 797, 840 N.E.2d 526, 532 (2006).

II.

BMS DID NOT OWN OR CONTROL AWPS

A. The Material Facts

As noted above, BMS did not report AWPs; it reported list prices. (Kaszuba Aff. ¶¶ 1-2.) For the BMS drugs at issue in the case, the list prices were the prices that appeared on invoices to wholesalers, and there were substantial sales at list price. (Szabo Decl. ¶¶ 2, 11; Bell BMS Decl. Exhs. D and E.) BMS did not control the mark-up factor that publications used to calculate AWPs, and it could not change what the publications did. (Kaszuba Aff. ¶¶ 2-3; Morgan Dep. Tr. 230, annexed to Edwards Decl. as Exh. D.)

Plaintiffs do not dispute these facts, except they contend that BMS "controlled" AWPs. (Pltfs.' Mem. at 15.) Plaintiffs cite no evidence that would refute BMS's evidence of lack of control, which includes the undisputed testimony of the BMS employees responsible for reporting AWPs, the undisputed testimony of the only witness who has testified on behalf of a publication and documents written in the regular course of business.[7] Indeed, the evidence plaintiffs cite establishes that "AWP is not determined or set by BMS," "AWPs are outside the control of BMS" and the mark-ups used to calculate AWPs "are set wholly at the discretion of the data services." (Pltfs.' BMS Exh. 23 at BMS/AWP/01088211, Exh. 34 at BMS/AWP 00442095, BMS/AWP 00442097.)[8]

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[7] See Kaszuba Aff. ¶ 2; Szabo Decl. ¶ 6; Morgan Dep. Tr. 230, annexed to Edwards Decl. as Exh. D; Kaszuba Dep. Tr. 97-101, annexed to Edwards Decl. as Exh. C; Tretter Decl. ¶¶ 3-5, Exhs. 2-4.

[8] Plaintiffs cite their BMS Exh. 34 only for the two phrases on that page which state that "AWPs can confuse the understanding of pricing within the US pharmaceutical system" and "we need to be careful of using AWPs because the name is misleading." Plaintiffs obviously seek to imply that BMS engineered the confusion. That is disingenous. Plaintiffs deliberately omit the words between their quotes that "AWPs are outside the control of BMS." (Id. at BMS/AWP/00442097.) In fact, the entire BMS Exh. 34 is an attempt to explain (a) the "legacy" of AWPs from the "pre-1980's" to "how the AWP is used today" and (b) how AWP is part of a system that was thrust upon BMS; not one for which BMS is responsible or has encouraged.

When plaintiffs assert that BMS "controlled" AWPs, the only facts they cite are that BMS reported list prices to the publications; it knew that the publications would apply a mark-up factor of 20% or 25% to calculate AWPs; and it reviewed those AWPs after they were calculated. (Pltfs.' Mem. at 15-16.) Similarly, when plaintiffs assert that BMS "owned" AWPs, they only facts they cite are that BMS and OTN included those AWPs in various documents, including documents that physicians could use to ascertain reimbursement amounts. (Id. at 18-19.)[9] The question is whether those facts make BMS responsible for the publications' AWPs; the answer to that question is clearly no.

B. Legal Analysis

In the BMS Defendants' Memorandum of Law in Support of Their Motion for Summary Judgment, dated March 15, 2006 ("BMS's Mem."), which is incorporated by reference herein, we noted that the mere provision of truthful information to a third party does not make BMS liable for the alleged deception by that third party. (BMS's Mem. at 8.) While the actions of the publications may well have been foreseeable, that is not sufficient, standing alone, to make BMS legally responsible for them. See, e.g., Mitzan v. Medview Servs., Inc., No. Civ.A. 98-01211, 1999 WL 33105613, at *9 (Mass. Super. June 16, 1999) ("that there may be a causal connection . . . is not itself sufficient to sustain a cause of action under Chapter 93A."); John Boyd Co. v. Boston Gas Co., 775 F. Supp. 435, 440 (D. Mass. 1991) ("the Supreme Judicial Court has stressed the existence of some contractual or business relationship between the parties as a precursor to liability under Chapter 93A"). Even where a party reviews and comments on the statements of a third party, it is not liable for the misstatements of that party unless it

[9] OTN's Network News and AWP Report included AWPs for all drugs marketed by OTN, not simply BMS drugs. (Pltfs.' BMS Exhs. 24-26.) This undercuts plaintiffs' theory that OTN published AWPs for BMS drugs in order to gain a competitive advantage.

intentionally fosters a mistaken belief concerning a material fact. In re Cabletron Sys., Inc., 311 F.3d 11, 38 (1st Cir. 2002).

Furthermore, it is undisputed that neither, the federal government nor any commercial payor was deceived by the mark up between list prices and AWPs. Plaintiffs' expert, Dr. Hartman, has conceded that both private payors and the federal government "expected" a mark-up of at least 30%. (Hartman Dep. Tr. 677-86, annexed to Edwards Decl. as Exh. J.) The federal government has conceded that "the spread between list price and AWP was known to the government in various ways and assumed by the Medicare reimbursement system." (Gov't Mem. in United States v. MacKenzie at 1, annexed to Edwards Decl. as Exh. I.)

Plaintiffs contend that "there is no evidence that BMS ever took any actions to either persuade publishers to report accurate AWPs or to publicize the inflated nature of the AWPs for BMS or other drugs." (Pltfs.' Mem. at 53.) In fact, BMS told the publications that its list prices did not reflect discounts, but it had no effect. (See Morgan Dep. Tr. 225-27, annexed to Edwards Decl. as Exh. D; Edwards Decl. F; see also Szabo Dec. ¶ 5.) It is difficult to imagine what more BMS could have done, other than (a) to change its list prices to reflect discounts or (b) to stop sending list prices to the publications. Whether BMS had an obligation to change its list prices to reflect discounts is discussed in the next section. BMS could not have stopped sending list prices to the publications, however, because it is undisputed that no payor will reimburse a provider for a drug unless it is listed with a price in one of the publications. (Kaszuba Dep. Tr. 220-22, annexed to Tretter Decl. as Exh. 1; Ihling Dep. Tr. 125-26, annexed to Tretter Decl. as Exh. 5.)[10]

[10] Medicare directed its carriers to consult the publications to determine reimbursement amounts. (Tretter Decl. Exhs. 6-8.)

BMS was not required to go out of business in order to avoid the consequences of the publications' conduct. As Dr. Berndt recognized, no single manufacturer was in a position to change the price reporting practices of the publications. (Report of Dr. Ernst R. Berndt, dated Feb. 9, 2005, ¶ 29-31.) Where, as here, a manufacturer simply follows industry practice, that cannot violate Mass. G.L. ch. 93A. See, e.g., Comm. Union Ins. Co. v. Seven Provinces Ins. Co. Ltd., 217 F.3d 33, 43-44 (1st Cir. 2000) (affirming judgment that reinsurer had engaged in unfair conduct under 93A based on, *inter alia*, expert testimony regarding "the traditional mores of industry"); Miniter Ins., 112 F.3d at 1251 (finding no 93A unfairness when insurer "adhered to the industry custom"); Govoni & Sons Const. Co. v. Mechanics Bank, 51 Mass. App. Ct. 35, 51 742 N.E.2d 1094, 1107 (Worcester Cty. 2001) (no violation of 93A where bank "was merely following procedures which, although resulting in improper payment, were widely used by similar banks in the area").

Plaintiffs' claim that BMS "owned" the AWPs for its drugs because it used them in internal and external documents adds nothing to the analysis. It is not unfair or deceptive for a company to have documents in its files. Nor was it unfair or deceptive for BMS to communicate AWPs to providers, who used them for their own internal purposes. (Peterson Dep. Tr. 150-154, annexed to Tretter Decl. as Exh. 9; Akscin Dep. Tr. 110-113, annexed to Berman Decl. as Exh. 4.)[11]

For these reasons, plaintiffs' claim that BMS is responsible for AWPs because it owns or controls them must fail.

[11] Plaintiffs do not contend that providers used the AWPs obtained from BMS to make misrepresentations to payors. For example, in processing a claim for reimbursement from Medicare, a physician does not identify an AWP. The physician simply fills out a form 1500, which includes the physician's actual charge, and submits it to Medicare, which calculates reimbursement based on its determination of the AWP. (Tretter Decl. Exh. 6, 8.)

III.

BMS DID NOT MANIPULATE THE "SPREAD"

A. The Material Facts

As noted above, when BMS launched the products at issue in this case, it selected a list price that was the price at which the product was actually sold. (Szabo Decl. ¶¶ 2, 11.) When the product faced competition, particularly after it lost patent protection, BMS offered discounts to meet that competition. (Id. ¶ 4.) Even then, BMS almost always realized significant revenue on the drugs at issue in the case in sale transactions within 5% of list price. (Bell BMS Decl. Exhs. D and E.)

Plaintiffs do not proffer facts that are inconsistent with these facts; rather, they accuse BMS of employing "secret discounting and rebating mechanisms." (Pltfs.' Mem. at 55.) They stress that discounts "were not made public by BMS or any publication, and would not be reflected in the WLP." (Id. at 58) (emphasis in original). The implication of plaintiffs' theory is that BMS's list prices should have been adjusted to reflect discounts, so those discounts would no longer be "secret."

B. Legal Analysis

As noted in BMS's memorandum in support of its motion for summary judgment, there is no legal basis for plaintiffs' contention that list prices must reflect discounts. (BMS's Mem. at 10.) Indeed, plaintiffs' own expert has testified that the term "list price" would suggest that it does not reflect discounts. (Rosenthal Dep. Tr. 390-91, annexed to Tretter Decl. as Exh. 10.) If this Court were to adopt a different rule, as plaintiffs suggest, it would radically transform the way companies do business in the United States.

1. The OIG guidance does not create a duty to disclose discounts

Plaintiffs assert that the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003), supports their position. (Pltfs.' Mem. at 44.) There are many reasons why that is not so, some of which are set forth in Defendants' Joint Memorandum in Opposition to Plaintiffs' Motion for Partial Summary Judgment. First, the OIG guidance is unclear, and the language on which plaintiffs rely does not refer to AWP – it refers only to Average Manufacturer Price and Best Price, which are prices that manufacturers report as part of the Medicaid program. The very case on which plaintiffs rely for the proposition that the Court should "defer" to the OIG held that such deference is inappropriate where the agency's reasoning is unclear. Harrington v. Chao, 280 F.3d 50, 59-60 (1st Cir. 2000).

Second, even if the OIG had clearly stated that list prices must reflect discounts, it has no statutory authority to make such a pronouncement. The OIG is an independent unit within the Department of Health and Human Services with responsibility for conducting and supervising audits and investigations, recommending policies, and keeping the head of the agency informed. Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101. Where, as here, an administrative body has not been granted any rule-making power, "its interpretive guidance is certainly not entitled to deference." Navarro v. Pfizer Corp., 261 F.3d 90, 99 (1st Cir. 2001).

Third, even if the OIG had rule-making authority, it does not have the power to undermine the intent of Congress. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously express intent of Congress." Chevron, U.S.A. Inc. v. Natural Res. Def. Council Inc., 467 U.S. 837, 842-43 (1984). As demonstrated in the Track 1 Defendants' Memorandum of Law in Support of Their Joint

Motion for Summary Judgment dated March 15, 2006 ("Joint Mem."), it is clear that Congress did not intend for AWP to reflect discounts. (Joint Mem. 6-9.)

Fourth, even if the OIG's guidance were consistent with Congress' intent, its acts are only entitled to Chevron deference where it is acting pursuant to formal rule-making authority. United States v. Mead Corp., 533 U.S. 218, 226-27 (2001). Otherwise, its interpretation is entitled to respect only to the extent that it has the power to persuade. Gonzales v. Oregon, 126 S.Ct. 904, 915 (2006). In this case, the OIG was not performing a rulemaking role and its views in 2003 are hardly persuasive evidence of what Medicare or Congress believed during the period 1991 through 2002 – especially in light of the massive evidence that both Medicare and Congress understood that AWPs did not reflect discounts. (Joint Mem. at 2-8.)

It should be emphasized that, if Medicare or Congress had wanted to establish a regime in which – contrary to other industries – list prices in the pharmaceutical industry were required to reflect discounts, they could have done so. The fact is they did not; and one of the reasons they did not is they affirmatively wanted reimbursement for drugs to exceed acquisition cost because reimbursement for the service of administering the drug was inadequate. (Joint Mem. at 8, 10.) For this reason, even if the OIG's guidance could be interpreted as suggesting list prices must reflect discounts, it would not be entitled to any deference because the effect "would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation." Christensen v. Harris County, 529 U.S. 576, 588 (2000).

2. There is no duty to disclose discounts under other laws

To the extent that plaintiffs contend that BMS had an independent duty to disclose discounts under Mass. G. L. ch. 93A, that contention is without merit. As BMS demonstrated in its memorandum in support of its motion for summary judgment, while the duty to disclose

under Mass. G. L. ch. 93A may be broad, it does not include a duty to disclose discounts. (BMS's Mem. at 10-14.) Courts interpreting Mass. G. L. ch. 93A have consistently held that the statute does not require disclosure of proprietary cost and pricing information. See, e.g., Whitehall Co. v. Barletta, 404 Mass. 497, 503-04, 536 N.E.2d 333, 337-38 (1989); Schwanbeck v. Federal-Mogul Corp., 31 Mass. App. Ct. 390, 405, 578 N.E.2d 789, 798 (Suffolk Cty. 1991) *rev'd on other grounds*, 412 Mass. 703, 592 N.E.2d 1289 (1992); AMI Mun. Vehicles Div. of Natick Auto Sales, Inc. v. Comm. of Mass. Dep't of Procurement and General Servs., No. 974392, 1998 WL 1284172, at *4 (Mass. Super. June 4, 1998).

The consumer protection statutes of other states have been interpreted by courts the same way. For example, in Kolari v. N.Y. – Pres. Hosp., 382 F. Supp. 2d 562 (S.D.N.Y. 2005), the plaintiff alleged that a hospital had violated New York's consumer protection statute by failing to disclose that insured patients received discounted prices. In granting the motion to dismiss, the court held that "the Hospital had no obligation to disclose to Plaintiffs the rates other patients would be charged." Id. at 577.

Similarly, courts have declined to interpret the federal False Claims Act to require a disclosure of discounts. Thus, in Gublo v. NovaCare, Inc., 62 F. Supp. 2d 347, 354 (D. Mass. 1999), Judge Stearns dismissed a claim that a manufacturer of orthotic and prosthetic devices had overstated its fees to Medicare by failing to include discounts, stating that "the relators fail to point to any section of the regulations that requires NovaCare to factor discounts given to private insurers to the determination of its 'actual charges' for government billing purposes." See also U.S. ex rel. Cox v. Iowa Health Sys., 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998) ("A standard billing practice within an industry could hardly be said to be false, when no controlling authority requires parties to submit claims in nautical rather than statute miles.").

In addition, courts have consistently held that there is no duty under the mail fraud statute to disclose discounts. See, e.g., Bonilla v. Volvo Car Corp., 150 F.3d 62, 69-70 (1st Cir. 1998); Langford v. Rite Aid of Alabama, Inc., 231 F.3d 1308, 1313 (11th Cir. 2000); Katzman v. Victoria's Secret Catalogue, 167 F.R.D. 649, 656 (S.D.N.Y. 1996), aff'd, 113 F.3d 1229 (2d Cir. 1997). Similarly, courts have held that there is no duty under the securities laws to disclose discounts. In re Stone & Webster, Inc., 253 F. Supp. 2d 102, 124 (D. Mass. 2003) ("[C]ourts have been wary about imposing on companies an affirmative duty to disclose to competitors sensitive pricing and marketing decisions.") (emphasis and internal quotes omitted).

Courts have also refused to require the disclosure of confidential pricing information in Freedom of Information Act cases. McDonnell Douglas Corp. v. Nat'l Aeronautics and Space Admin., 180 F.3d 303, 305-306 (D.C. Cir. 1999) (citing FOIA "Exemption 4" on sensitive commercial and financial information); Shermco Indus., Inc. v. Secretary of the Air Force, 613 F.2d 1314, 1317 (5th Cir. 1980) (same). And courts have consistently protected pricing information in determining whether to grant protective orders. See, e.g., GTE Prods. Corp. v. Gee, 112 F.R.D. 169, 171 (D. Mass. 1986).

Indeed, there is a strong public policy against the disclosure of discounts. As the Supreme Court recognized in Great Atlantic & Pacific Tea Co. v. FTC, 440 U.S. 69, 80 (1979) (quoting United States. v. Container Corp. of America, 393 U.S. 333 (1969)):

> In a competitive market, uncertainty among sellers will cause them to compete for business by offering buyers lower prices. Because of the evils of collusive action, the Court has held that the exchange of price information by competitors violates the Sherman Act.

The Court added that "a duty of affirmative disclosure [of transaction prices] would almost inevitably frustrate competitive bidding and, by reducing uncertainty, lead to price matching and anticompetitive cooperation among sellers." Great Atlantic, 440 U.S. at 80. (See also Letter

from S. Creighton to Assemblyman Aghazarian, dated Sept. 7, 2004, at 10, annexed to Edwards Decl. as Exh. K.)

Even where there is a fiduciary relationship, this Court has held that there is no duty to disclose discounts. Thus, in Alves, this Court ruled that a health plan, which gave its beneficiaries receipts that listed the "retail value" of prescription drugs, did not have to disclose that it had actually acquired the drugs at substantial discounts below retail value. 204 F. Supp. 2d at 212. This Court noted that "the receipt, purporting to compare the copayment 'retail value' of each medication, does in fact provide precisely such a comparison." Id. Similarly, here, BMS's list price is precisely what it purports to be, and requiring BMS to publish list prices that would reflect discounts would turn it into something other than a list price.

Plaintiffs contend that, having disclosed partial information that may be misleading, BMS had a duty to ensure that AWPs were not misleading. (Pltfs.' Mem. at 124.) However, BMS did not disclose partial information that could be misleading. BMS disclosed list prices that were not misleading. As one of the cases cited by plaintiffs states, there is no affirmative duty to disclose information just because it may be material. Roeder v. Alpha Indus., Inc., 814 F.2d 22, 27 (1st Cir. 1987) (citing numerous authorities for the proposition that "[t]he prevailing view is that there is no such affirmative duty to disclose").

Plaintiffs allege that there were circumstances in which manufacturers artificially increased list prices, as opposed to offering discounts, as a way of providing an inducement to physicians without reducing revenue. (Pltfs.' Mem. at 46.) That did not happen with BMS.[12] During the class period, with minor exceptions, the list prices for all but three of the subject

[12] Plaintiffs point to a launch plan for one drug, Etopophos, as evidence that BMS manipulated the spread by lowering the AWP for a competing BMS drug, Vepesid, and increasing the AWP for Etopophos. (Pltfs.' Mem. at 59-60.) As plaintiffs' expert Dr. Rosenthal admitted, however, BMS did not implement that plan. (Rosenthal Dep. Tr. 376-384, annexed to Tretter Decl. as Exh. 11.)

drugs (Paraplatin, Vepesid capsules and Cytoxan tablets) remained the same. (Edwards Decl. Exh. A at attachment G.2.b) In those cases where list price increased, BMS obtained substantial sales at the increased price. (Bell BMS Decl. Exhs. D and E.)

There is no basis for plaintiffs' claim that BMS "manipulated" list prices.

IV.

BMS DID NOT "MARKET" THE SPREAD

A. The Material Facts

As noted above, from time to time, BMS's sales representatives responded to customer questions concerning reimbursement. OTN also made reimbursement information available to customers on all of the drugs that it distributed, not simply BMS drugs, through such mechanisms as the AWP Report. Plaintiffs do not contend that this information was deceptive in any way; rather, plaintiffs contend that this constitutes improper "marketing" of the spread.[13]

B. Legal Analysis

Plaintiffs rely on the OIG guidance to suggest that it is illegal to "market" the spread. (Pltfs.' Mem. at 44-45.) The OIG guidance in fact states: "The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." 68 Fed. Reg. at 23737 (emphasis added). As demonstrated above, BMS did not manipulate the spread.

Moreover, in addition to the fact that the OIG's guidance is not entitled to deference for the reasons set forth above, the guidance itself states that "[t]he contents of this guidance should not be viewed as mandatory" and "[t]he document is intended to present

[13] It is difficult to see how OTN's actions could constitute "marketing" the spread, since that concept assumes that the spread was used to gain a competitive advantage and OTN distributed the drugs of many manufacturers.

voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers." Id. Furthermore, the guidance states that the section relied upon by plaintiffs "is not intended to imply that the practice or activity is necessarily illegal in all circumstances" and that it is "not intended to present detailed or comprehensive summaries of lawful and unlawful activity." Id.

In addition, as demonstrated in BMS's memorandum in support of its motion for summary judgment, providing accurate information to customers about reimbursement is not a deceptive or unfair act. (BMS's Mem. at 14-16.) Moreover, even if the act of responding to a customer question concerning spread could be deceptive or unfair, there is no way such an act could have caused monetary injury to Medicare or to the class members. A sales representative's statement to a physician has no effect whatsoever on the reimbursement rate under Medicare Part B. Massachusetts courts have consistently held that in an action under Chapter 93A, plaintiffs must prove a "causal connection between the seller's deception and the buyer's loss." See, e.g., Hershenow, 840 N.E. 2d at 528. Plaintiffs cannot demonstrate a causal connection here.

V.

MEDICARE WAS NOT DECEIVED

As demonstrated in the Track 1 defendants' joint memorandum in support of their motion for summary judgment, in order to prevail in this case plaintiffs would have to show that Medicare was deceived. (Joint Mem. at 15-21.) Plaintiffs cannot show that because it is undisputed that Medicare understood that "AWP is not a reliable indicator of the costs of a drug to physicians." (Edwards Decl. Exh. M at 2.) It is also undisputed that, at least as early as October 2, 1996, Medicare was aware that reported AWPs could result in "profit margins of more than 500% and in some instances, more than 1000%." (Edwards Decl. Exh. L at 3.)

Medicare was particularly aware of the spread on BMS drugs that were subject to generic competition. The spreads for at least three of the BMS injectible drugs – Cytoxan, Rubex and Vepesid – were disclosed in documents received by Medicare. (Edwards Decl. Exh. M at App. III.) Those same documents demonstrate that the government was tracking the spreads of at least one other drug, Blenoxane. (Id.) The spreads for two other single-source drugs – Etopophos and Paraplatin – were negligible, and the spreads for Taxol did not become significant until 2002, after Taxol became subject to generic competition and after this litigation began. (Bell BMS Decl. ¶ 48 and Exhs. D and E.)

It is well-established that there can be no claim of unfairness or deception where the alleged victim knows the truth. In Brazas, for example, the First Circuit affirmed the granting of summary judgment where it found that a "reasonable insured" would have understood the scope of his coverage simply by reading the insurance policy. 220 F.3d at 9. Similarly, in Dinjian, the court found that the plaintiff had failed to make out a factual case of unfairness or deception where the plaintiff knew that his advisor had an interest in a loan but was not informed of the nature of that interest. 22 Mass. App. Ct. at 597, 495 N.E.2d at 888.

Furthermore, knowledge of the truth eliminates any possible causal connection between the alleged deception and the alleged injury. See, e.g., Tagliente v. Himmer, 949 F.2d 1, 7-8 (1st Cir. 1991) (purchaser knew of alleged defect); Mass. Farm Bureau Fed., Inc. v. Blue Cross of Mass., Inc., 403 Mass. 722, 731, 532 N.E.2d 660, 665 (1989) (insurer understood transaction). Here, HCFA and Congress knew about "megaspreads," but they took no action. See Cathay Pac. Airways, Ltd. v. Fly and See Travel, Inc., 3 F. Supp. 2d 443, 451 (S.D.N.Y 1998) (decision to voluntarily pay notwithstanding knowledge of alleged fraud was intervening cause). Since plaintiffs bear the burden of demonstrating causation, BMS – not plaintiffs – is

entitled to summary judgment on this issue. See, e.g., Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) ("[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.").

In sum, all of plaintiffs' claims depend on the premise that Medicare was deceived. Even if, contrary to fact, BMS were responsible for AWPs, BMS manipulated AWPs and BMS marketed the spread, that would make no difference if Medicare was not deceived. We believe it is undisputed that Medicare was not deceived; but if the Court is not sufficiently convinced so as to grant judgment for BMS, there is an issue of fact with respect to that question which precludes granting summary judgment for plaintiffs.

VI.

PLAINTIFFS' THEORY DOES NOT MAKE SENSE

At bottom, plaintiffs contend that BMS should have adjusted its list prices to produce AWPs that were either equal to average sale prices ("ASPs") or only exceeded ASPs by a predictable amount (according to plaintiffs' expert, Dr. Hartman, that amount should not have been greater than 30%). (Hartman Dep. Tr. 685-86, annexed to Edwards Decl. as Exh. J.) In BMS's case, it would have been impossible to create a list price that results in an AWP that equals ASP because the publications automatically mark up the list price by 20% to 25%. No customer would contract with BMS to pay a price that was higher than BMS's own list price. Even if the permissible spread were 30%, as Dr. Hartman would have it, that would give BMS only 5% to 10% of "headroom" off of list price in which to offer discounts.

More fundamentally, plaintiffs' theory is totally at odds with economic concepts and industry practices. The practices in this industry are the product of literally thousands of decisions and compromises that were designed to achieve an appropriate balance between the goal of providing cost effective healthcare for millions of Americans and providing adequate compensation for providers such as oncologists. Plaintiffs' theory would alter that balance by reducing or eliminating the profits or "spread" that providers could earn on physician-administered drugs without regard to the effect of that change on such issues as whether providers would continue to operate independent clinics and whether providers would insist on additional compensation for services.

Furthermore, plaintiffs' theory would result in higher, not lower, prices. If spreads were eliminated, prices would go up because providers would be indifferent to the cost of drugs and manufacturers would have no incentive to discount. If spreads could not exceed 30%, then providers would prefer higher priced drugs because 30% of a higher number would result in greater provider profits.

Plaintiffs accuse BMS of "gouging elderly Medicare Part B beneficiaries" (Pltfs.' Mem. at 122), but nothing could be further from the truth. The oncology products at issue in this case have saved people's lives. BMS undertook the risk and expense of developing those products and then marketed them in accordance with the rules. As demonstrated above, if plaintiffs' theory of the case is correct, then the only way BMS could have avoided liability would have been to minimize discounting or refrain from reporting any prices to the publications, which would have made it impossible for BMS to sell its products. Neither result would have been in the interests of the class members that plaintiffs purport to represent.

Conclusion

For all the foregoing reasons, BMS respectfully requests that the Court deny plaintiffs' summary judgment motion on the claims of Classes 1 and 2 and instead grant BMS's summary judgment on those claims.

Dated: Boston, Massachusetts
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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on April 7, 2006 a true and correct copy of the forgoing BMS DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter
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